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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

PTOL-90A (Rev. 04/07)

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *30 July 2007*.

2a) ☒ This action is **FINAL.**   2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5, 7-12 and 14-19* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-5, 7-12 and 14-19* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

1.   This communication is in response to the amendment received on 07/30/2007.

Claims 6, 13 and 20 have been canceled. Claims 1, 8 and 15 have been amended.

Claims 1-5, 7-12 and 14-19 remain pending in this application.

Double Patenting

2.   The nonstatutory double patenting rejection is based on a judicially created
doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the
unjustified or improper timewise extension of the "right to exclude" granted by a patent
and to prevent possible harassment by multiple assignees.   A nonstatutory
obviousness-type double patenting rejection is appropriate where the conflicting claims
are not identical, but at least one examined application claim is not patentably distinct
from the reference claim(s) because the examined application claim is either anticipated
by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140
F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29
USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir.
1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422
F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ
644 (CCPA 1969).

3.   A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d)
may be used to overcome an actual or provisional rejection based on a nonstatutory
double patenting ground provided the conflicting application or patent either is shown to
be commonly owned with this application, or claims an invention made as a result of
activities undertaken within the scope of a joint research agreement.

4.   Effective January 1, 1994, a registered attorney or agent of record may sign a
terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with
37 CFR 3.73(b).

5.   Claims 1, 8 and 15 are rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,381,576 B1.

Although the conflicting claims are not identical, they are not patentably distinct from

each other because the codes recited in the amended claim repeats the same code

structure recited in claim 1 of U.S. Patent No. 6,381,576 B1. Amended claim 1 recites a

method, comprising the steps of: receiving test result variable code, receiving a protocol

choice corresponding to the test result variable code, receiving a treatment code

determining whether the treatment code corresponds to the protocol choice and storing

the test result variable code, protocol choice and treatment code; <u>wherein the test result</u>

<u>variable code, protocol choice and treatment code are stored in a static data structure</u>

<u>comprising: a first code uniquely identifying a protocol grouping assigning priorities to</u>

<u>one or more protocol choices based on a range of one or more disease variable values;</u>

<u>a second code identifying a protocol choice selected from the protocol grouping and a</u>

<u>justification for selecting the protocol choice; a third code identifying each procedure,</u>

<u>diagnostic test, or treatment performed pursuant to the protocol choice and a</u>

<u>justification for selecting each respective procedure, diagnostic test, or treatment; and a</u>

<u>fourth code defining a charge code for all procedures, diagnostic tests, and treatments</u>

<u>performed.</u> It would have been obvious to one having ordinary skill in the art at the time

of the invention that, in order to have the test result variable code, protocol choice and

treatment code stored in a static data structure, these codes need to be received.

Therefore the steps of receiving and storing these codes would be obvious.

6.   Similarly, the data processing system claim 8 recites at least a processor and an

accessible memory, comprising: circuitry for the steps of method claim 1. The

obviousness of receiving the codes and storing them in a data structure is as addressed

above for claim 1.

7.   Amended claim 15 recites a computer program product having computer

readable code in a computer-readable medium, comprising: instructions for the steps of

method claim 1. The obviousness of receiving the codes and storing them in a data

structure is as addressed above for claim 1.

Claim Rejections - 35 USC § 112

8.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

9.   Claims 1-5, 7-12 and 14 rejected under 35 U.S.C. 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

A. As per claims 1, 8 and 15, it's not clear which protocol choice is identified by

the second code; is it the received protocol choice or another protocol choice

since the second limitation of the claim recites "receiving a protocol choice

corresponding to the test result variable code".

B. System claim 8 and computer program product claim 15 repeat the same

limitation, therefore are rejected under 35 U.S.C. 112, second paragraph as

explained in the rejection of claim 1 above and incorporated herein.

Claim Rejections - 35 USC § 102

10.   The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11.   Claims 1-5, 7-12 and 14-19 are rejected under 35 U.S.C. 102(e) as being

unpatentable by McIlroy et al. (hereinafter McIlroy) (U.S. Patent No. 5,953,704).

A. Claim 1 has been amended now to recite a method, comprising the steps of:

i.   receiving a test result variable code (McIlroy; abstract, col. 10, lines 9-19);

ii.   receiving a protocol choice corresponding to the test result variable code (McIlroy; col. 6, lines 13-17, col. 10, lines 9-19, Figure 9b);

iii.   receiving a treatment code (McIlroy; col. 12, lines 53-65, col. 13, lines 11-25);

iv.   determining whether the treatment code corresponds to the protocol choice (McIlroy; col. 5, lines 35-45); and

v.   storing the test result variable code, protocol choice and treatment code (McIlroy; col. 4, lines 38-48, col. 12, lines 29-32).

vi.   wherein the test result variable code, protocol choice, and treatment code are stored in a data structure comprising:

(1)   a first code uniquely identifying a protocol grouping assigning priorities to one or more protocol choices based on a range of one or more disease variable values (McIlroy; col. 4, line 62 to col. 5, line 8, col. 12, lines 53-65, Figure 16);

(2)   a second code identifying a protocol choice selected from

the protocol grouping and a justification for selecting the protocol

choice (McIlroy; col. 12, lines 53-65, Figure 16);

(3)   a third code identifying each procedure, diagnostic test, or

treatment performed pursuant to the protocol choice and a

justification for selecting each respective procedure, diagnostic test,

or treatment (McIlroy; col. 13, lines 11-25); and

(4)   a fourth code defining a charge code for all procedures,

diagnostic tests, and treatments performed (McIlroy; col. 13, lines

26-38).

McIlroy teaches a health care management system for use by hospitals,

physicians, insurance companies, health maintenance organizations, and others in the

health care field includes a processing unit and health condition guidelines. A user

inputs information related to the health condition of an individual and guideline treatment

options are identified (abstract). And McIlroy teaches a system 300, which is a set of

diagnosis-based guidelines that are derived from medical professional and healthcare

management expertise. Each guideline is associated with a particular health care

condition for which treatment exists. Each guideline is intended to lead a system user

through a sequence of interactive data-collection queries based on the specified

healthcare condition observed in an individual patient... As implemented in the system

300, a guideline can be viewed as a decision tree with multiple data collection nodes,

most of which have conditional branching to connected nodes based on user-supplied

data. The endpoints of navigation through the decision tree are usually embodied in a

set of treatment options. The path to any treatment option involves one or more

conditional branches. Thus, each guideline implemented in the system 300 has a

definite algorithmic structure that guides the user. (col. 4, line 62 to col. 5, line 20).

McIlroy does not expressly teach the specific data recited in claims 1, 8 and 15;

however, these differences are only found in the non-functional descriptive material and

are not functionally involved in the steps recited nor do they alter the recited structural

elements. The recited method steps would be performed the same regardless of the

specific data. Further, the structural elements remain the same regardless of the

specific data. Thus, this descriptive material will not distinguish the claimed invention

from the prior art in terms of patentability, *see In re Gulack, 703 F.2d 1381, 1385, 217*

USPQ 401, 404 (Fed. Cir. 1983); In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed.

Cir. 1994); MPEP ☏ 2106.

> B. As per claim 2, McIlroy discloses the method of claim 1, further comprising
>
> the step of displaying a set of protocol choices corresponding to the test result
>
> variable code, from which the protocol choice may be selected (McIlroy; col. 5,
>
> lines 9-20).
>
> C. As per claim 3, McIlroy discloses the method of claim 1, further comprising
>
> the step of displaying a set of treatment codes corresponding to the protocol
>
> choice, from which the treatment code may be selected (McIlroy; col. 5, lines 9-
>
> 20).

D. As per claim 4, McIlroy discloses the method of claim 1, further comprising the step of displaying a warning if the treatment code does not correspond to the protocol choice (McIlroy; col. 13, lines 26-29).

E. As per claim 5, McIlroy discloses the method of claim 1, further comprising the step of receiving a justification for at least one of the protocol choice and the treatment code (McIlroy; col. 5, lines 45-53).

F. As per claim 7, McIlroy discloses the method of claim 1, wherein the test result variable code, protocol choice and treatment code are analyzed for cost accounting and to determine clinical appropriateness (McIlroy; col. 8, lines 45-64).

G. As per claims 8-12 and 14, they are system claims, which repeat the same limitations of claims 1-5 and 7, the corresponding method claims, as a collection of elements as opposed to a series of process steps. Since the teachings of McIlroy disclose the underlying process steps that constitute the methods of claims 1-5 and 7, it is respectfully submitted that they provide the underlying structural elements that perform the steps as well. As such, the limitations of claims 8-12 and 14 are rejected for the same reasons given above for claims 1-5 and 7.

H. As per claims 15-19, it is an article of manufacture claim which repeats the same limitations of claim 1-5 and 7, the corresponding method claim, as a collection of executable instructions stored on machine readable media as opposed to a series of process steps. Since the teachings of McIlroy disclose

the underlying process steps that constitute the method of claim 1-5 and 7, it is

respectfully submitted that they likewise disclose the executable instructions that

perform the steps as well. As such, the limitations of claim 15-19, are rejected

for the same reasons given above for claim 1-5 and 7.

Response to Arguments

12.   Applicant's arguments filed 07/25/2007 have been fully considered but they are

not persuasive. Applicant's arguments will be rejected in the order in which they appear.

A. In response to applicant's argument that the references fail to show certain

features of applicant's invention, it is noted that the features upon which applicant

relies (i.e., creation of a static data structure) are not recited in the rejected

claim(s). The claims recite "the test result variable code, protocol choice and

treatment code are stored in a static data structure". Although the claims are

interpreted in light of the specification, limitations from the specification are not

read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057

(Fed. Cir. 1993).

Conclusion

13.   **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time

policy as set forth in 37 CFR 1.136(a).

14.   A shortened statutory period for reply to this final action is set to expire THREE

MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later

than SIX MONTHS from the mailing date of this final action.

15.   Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Dilek B. Cobanoglu whose telephone number is 571-

272-8295. The examiner can normally be reached on 8-4:30.

16.   If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Joseph Thomas can be reached on 571-272-6776. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

17.   Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DBC
A.U. 3626
10/15/2007

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